The professional, legal, and ethical dimensions of prescribing: Part 2 - legal and ethical

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ABSTRACT

This article continues the exploration of selected dimensions of prescribing practice, with a focus on the legal and ethical aspects. In Part 1 a new prescribing consultation model “RAPID-CASE” (Gould and Bain, 2022) was used to demonstrate ~~application of key pr~~ofessional principles to prescribing practice. This article examines pertinent underpinning laws and ethical principles that guide decision-making for prescribing.

KEYWORDS

prescribing; law; ethics; legal; nurse prescribing; non-medical prescribing; primary care

INTRODUCTION

Prescribing by the range of practitioners has develop over the years through a series of amendments to medicines law. These have resulted in an incremental expansion of prescribing rights and by implication, the scope for which the practitioner owes a duty of care. Spanning across the three dimensions, duty of care is integral to

professional standards, a recognised legal concept (Griffith, 2019) and underpins common ethical principles (Beauchamp and Childress, 2004). There is potential for overlap or conflict between these areas, as for example, there may be an ethical imperative to treat the person in front of you, but questions may arise about whether the situation is within your current scope of practice. Being able to justify or explain decisions as part of a duty of care is supported through application of a model such as the RAPID-CASE prescribing consultation model (Gould and Bain 2022). This article examines selected legal and ethical principles for prescribing decision making to prompt consideration of these when faced with practical challenges.

Legal context of the authority to prescribe

The Nursing and Midwifery Council (NMC), the General Pharmaceutical Council (GPhC) and the Health and Care Professions Council (HCPC) each hold the legal authority to admit qualified practitioners to the register, annotate their record with additional qualifications, suspend or remove registrants, as well as setting the educational standards for identified qualifications. ‘Prescribing professionally’ (RPS, 2021) involves being responsible for and understanding the ethical and legal implications of prescribing, while acting within legal and regulatory frameworks that affect prescribing practice. Practising professionally includes an awareness of laws underpinning prescribing such as the legal authority to prescribe, mechanisms for prescription writing, controlled drug laws, off-label or unlicensed medicines, supplementary prescribing, consent, capacity, and the legal duty of care (GMC 2021, HCPC 2022, RPS 2021, NMC 2018b).

Medicines law has been enacted across numerous parliamentary Acts, European Union (EU) legislation, and secondary legislation. It is helpful to know key reference points underpinning the legal authority to prescribe, the limits to that legal authority and the mechanisms by which prescriptions can be issued or medicines supplied. Not all four UK countries have the same legislation, due to devolved legislature, although laws for England and Wales tend to be similar while there are some marked differences for Scotland and Northern Ireland. Part of a prescriber’s duty is to be aware of pertinent legislation and updates to this for their respective countries. Table 1 illustrates the three main sources of law with Table 2 focusing on prescribing laws.

Table 1 - **Primary sources of law**

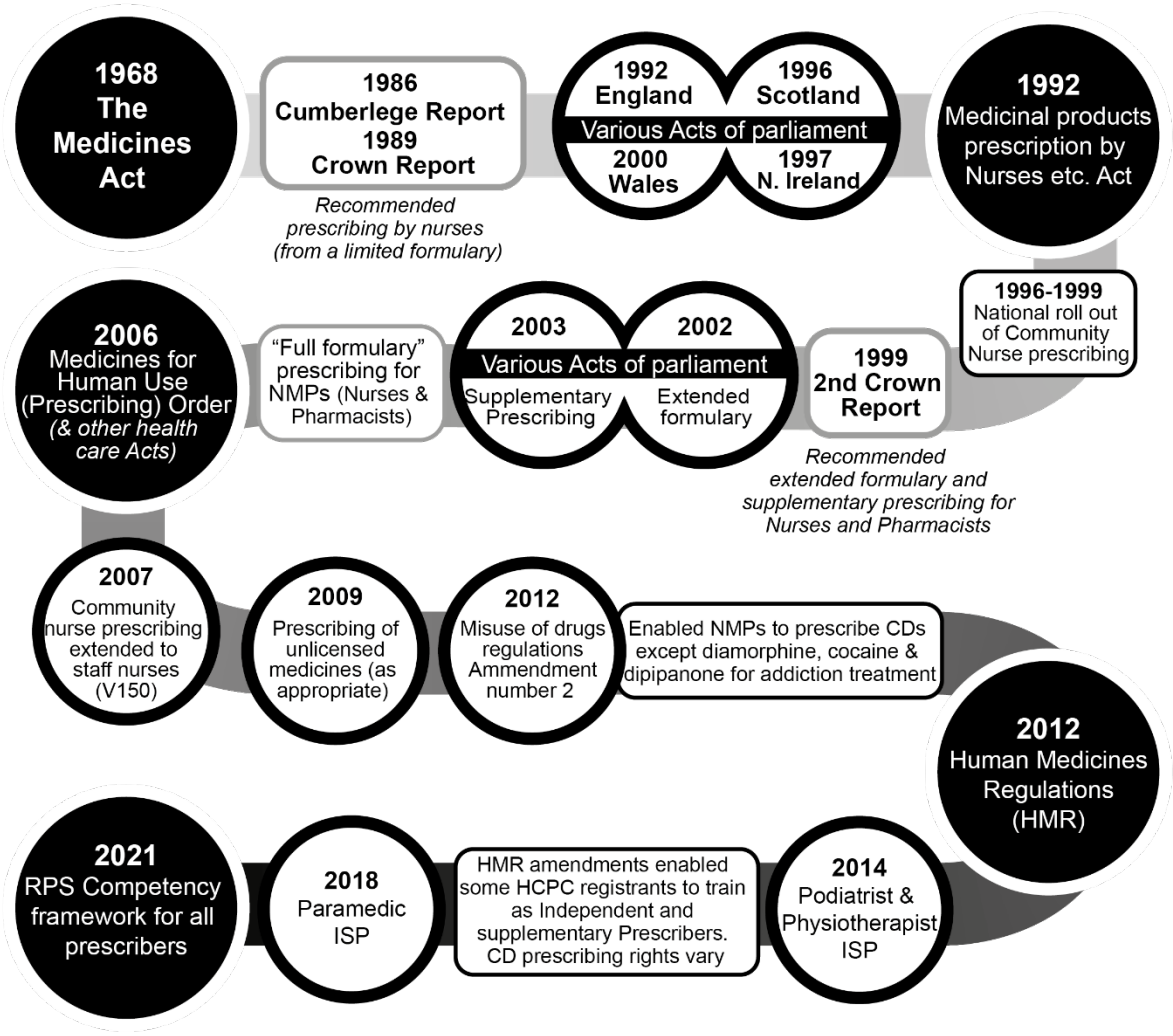
1. Legislation	2. Judicial Decisions	3. Human Rights and European Community law
1. **Primary:** Parliamentary Acts (Statute law) 2. **Secondary:** Statutory Instruments	**"Common Law"** Outcomes from court cases become common or case law and set the standard for how the law is applied. Decisions made in a higher court overrule lower courts. The hierarchy is: 1. Lower courts (e.g. Crown or magistrates court) 2. The High Court 3. The Court of Appeals, 4. The UK Supreme Court	*Embedded in UK law through Acts of parliament*. **Human Rights laws:** incorporated through the Human Rights Act (1998) **EU law:** Previously the European Community Act (1972) Since Dec. 2020, EU law is part of UK domestic legislation. Some types of EU legislation directly apply; noted on legislation.gov.uk as 'legislation originating from the EU'.

Sources: Griffith and Tengnah (2020) and UK Legislation (2021)

The main sources of legislation underpinning prescribing derive from Acts of Parliamentary (statute law) and secondary legislation (e.g. statutory instruments) along with European Community law. Regulations are not laws, but impact on what can legally be prescribed or sold.

Laws aim to safeguard the public, as for example, the Medicines Act [1968] was prompted by the thalidomide tragedy. The Medicines Act [1968] which covered prescribing by Doctors and Dentists, is not entirely repealed, but most of it has been replaced or superseded. For example, it was amended by the Medicinal Products; Prescription by Nurses etc. Act [1992] in response to reports that proposed nurse prescribing would improve efficiency and quality (DHSS, 1986; DHSC, 1989). While this only allowed prescribing by Health Visitors or District Nurses from a limited formulary for nurse prescribers, it evaluated extremely well, paving the way for a series of extensions to prescribing rights. Community practitioner nurse or midwife prescribers (denoted by V100 or V150), continue to be limited to a select number and type of products from the Nurse Prescribers' Formulary (NICE, Nurse Prescribing Advisory Group (NPAG)), other restrictions such as the strength of certain products, and are generally unable to prescribe 'off-license' or unlicensed preparations (PSNC, 2021). An overview of the timeline of key legislation can be found in Figure 1.

Figure 1 – A timeline of key prescribing legislation



Adapted from: Gould and Bain (2022)

Ten years after the initial 1992 legislation was the establishment of "extended formulary prescribing" [Prescription Only Medicines (Human Use) Amendment Order, 2002] followed closely by "dependent" or supplementary prescribing [National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc.) (England) Regulations 2003]. The second Crown Report (DHSS, 1999) eventually led to much wider prescribing rights for nurse and pharmacist prescribers through the Medicines for Human Use (Prescribing) Order [2006]. While that opened most of the British National Formulary to nurses and pharmacists who undertook a recognised educational programme, there were still tight restrictions on controlled drugs. The

Human Medicines Regulations (HMR) [2012] consolidated over 200 separate pieces of law, orders, regulations, statutory instruments, or European directives that had built up over the years, including those concerning prescribing by healthcare professionals other than medics (Griffith, 2012).

Prescribing also concerns legislation for controlled substances (Misuse of Drugs Act (MDA) 1971 and Misuse of Drugs Regulations (MDR), 2001) with amendments in 2012 for nurses and pharmacists, and at later dates for Allied Health professionals. Working within their scope of practice, nurses, midwives (V300) and pharmacists can legally prescribe any item from the British National Formulary (BNF), apart from three specific controlled drugs for addiction treatment (HMR [2012], Misuse of Drugs regulations amendment [2012], NICE, 2021). Allied Health Professionals have further differences for restrictions on controlled drugs, and only some Health Care and Professions Council registrants can train to prescribe (HCPC 2022). Knowing what you can legally prescribe is necessary, and familiarity with common controlled drugs is helpful. These are listed by Class (MDA, 1971) or Schedule (MDR, 2001) (Home Office, 2019).

Safety is linked to professional practice but is also implicated in fulfilling the legal duty of care. In the legal context, this refers to the obligation to act in a person's best interest, to ensure no act or omission results in harm, to act safely within areas of competence, and to provide advice about the risks and benefits of treatment (Griffith, 2018, 2019). Meeting this standard involves a comprehensive assessment and consideration of evidence-based treatment options. Clinical negligence is when the duty of care is breached causing physical or mental harm. It needs to be proven that the care or treatment was below the expected standard and the harm resulted from this. An example for leg ulcer care, would be an inaccurately performed doppler assessment that failed to detect arterial disease, resulting in compression damage, leading to amputation. In cases where harm has occurred, a claim of negligence through civil or tort law could be brought by the person who suffered harm (or their family) to compensate for the harm. Court rulings have established that successful negligence cases require three key features:

- *a duty of care was owed by the practitioner;*
- *this duty to the patient was breached*
- *the breach of duty caused loss or harm recognised by the courts.*

(Griffith, 2019)

The seminal legal case determining judgements around whether a breach of duty occurred was Bolam v Friern Hospital Management Committee [1957], often referred to as the “Bolam test”. This ruling suggested the professional is not negligent if their actions are aligned with accepted practice of their peers. While the Bolam test was the benchmark for many years, it was seen to extend beyond its intended limits and risk subjectivity. The Bolitho ruling [Bolitho v City and Hackney Health Authority [1997] 4 All ER 771] suggested a need for a logical basis underpinning the standard of care and is now more likely to be used (Samanta et al, 2003). The implication of this change for professionals and prescribers is the ability to show clear reasoning for decision-making in health care. This reflects a greater emphasis on evidence-based care, guidelines, and support for informed decision-making. Using a model such as “RAPID-CASE” can help guide the justification and rationale for decisions.

A less-discussed allegation in the Bolam case was the failure of the doctor to inform Mr. Bolam of the risks of the procedure. The UK Supreme Court judgement in Montgomery v Lanarkshire Health Board (2015) addressed duty of care in relation to the disclosure of information in relation to the risks of treatment or alternatives. Interpreting its practical significance, Chan (2017, p.2) states “*the Montgomery decision redefined the standard for informed consent and disclosure*”. The ruling reiterated the person’s right to make their own decisions while asserting that professionals must provide information about “*the material risks inherent in the treatment”* (Montgomery vs Lanarkshire, 2015, P.6). Clinical judgement is implied in determining which risks are material (e.g. if the person would think it is significant), or whether communicating the risk could be detrimental. Key information needs to be communicated in a sensitive and understandable way, but this may be challenging with more complex conditions or management regimes, particularly where they span across a range of specialisms. This legal ruling has strengthened the policy commitment to a person-centred approach while the RPS (2021) unambiguously include shared decision-making and providing information as core competencies for prescribers.

While the key aim in assessing and managing care is to facilitate informed choice, NICE (2019) identified barriers including: professionals' belief they already practice in this way, a lack of decision aids, the belief people don't want to be involved in their decisions, along with time or priority pressures. Practical influences on informed choice include communication barriers, the person's capacity and understanding of the health issue. Consent for assessment, treatment, advice or for using a person's information is required (GMC, 2020). Clinically, consent increases the likelihood of confidence in and cooperation with the treatment, and legally, without consent a practitioner can be charged with 'ill-treatment', 'assault' or 'trespass to the person' (Griffith and Tengnah, 2011). Valid consent needs to be full, free and informed (Griffith and Tengnah, 2011). These requirements imply that the person being treated comprehends the information being provided.

Having the mental capacity to consent means demonstrating an understanding of given information and using it to support decisions (DCA, 2013). Although someone may be assessed as having mental capacity, it is not unusual to prescribe treatments for people whose health decline, have fluctuating mental capacity or may not fully understand the treatment. Duty of care extends beyond the prescription, so when capacity is compromised it is important to consider harm that may occur. Examples include people with chronic obstructive pulmonary disease who are prescribed anticipatory medicines to take when their condition worsens, with the risk that their oxygen levels can cause confusion, or in people with worsening infections developing sepsis or entering a delirium state. In cases where people are unable to give or express consent, the Mental Capacity Act (MCA) [2005], is the legal framework enabling practitioners to act and make decisions on their behalf. The MCA code of practice (DCA, 2013) guides its use in aiming to ensure that decisions taken on behalf of someone lacking capacity, are made in their best interests (DCA, 2013). In practice, this can be challenging as although there is an assumption of mental capacity, assessment can be affected by communication problems, such as hearing loss or language barriers or there may be undiagnosed or fluctuating dementia. Even where mental capacity is compromised, appropriate support must be given to facilitate people in making their own decisions, or to optimise their involvement in decision-making processes (DCA, 2013). Fulfilling the legal duty of care involves being aware of risks, making justifiable decisions and recording these

coherently. There may also be ethical aspects, such as the balance between paternalism with an overly authoritative approach, weighed against the risks of promoting autonomy where people may be vulnerable.

Ethical dimensions of prescribing

Ethics or 'moral philosophy' involves considering fundamental questions around what is right and wrong. For professionals, this includes our moral code and the need to be aware of our value system as it can consciously or unconsciously influence our decisions. Östman et al (2019) describe ethics as universal rules of conduct that help guide our actions, intentions, and motives. Familiarity with professional and ethical principles helps practitioners examine decisions and unpick the complex challenges of clinical practice. When making clinical decisions moral analysis can begin when there is confusion about competing alternatives for action, or when professionals' values and those of the family are in conflict about what is in the best interest of the person in our care or in dilemmas where none of the alternatives are fully adequate.

Beauchamp and Childress (2004) noted four core principles of biomedical ethics of pertinence to healthcare settings. These include beneficence (providing benefit); non-maleficence (avoiding harm); respect for autonomy (respecting decision making); and justice (fair distribution of risks and benefits) (Beauchamp and Childress, 2004). Beneficence or producing benefit, entails doing 'good' for the people in our care and is fundamental to practice, and integral to professional codes. While it appears straightforward, it can become complicated when balancing benefits and risks, or when considering whose perception of 'good' is given more credence. For example, it is clear to community nurses that the significant benefits of compression bandaging outweigh the risks of discomfort or harm, and in terms of evidence-based practice, it is considered the 'gold standard' (NICE, CKS, 2021a). However, for the person in receipt of care, the discomfort may be seen to eclipse this benefit, particularly when it is impeding other aspects of their life. Beneficence can involve considering others' views, alongside the risks, benefits, costs and varying perspectives of diagnosis or treatment options.

While the principle of non-maleficence may seem to be the same as beneficence, it is more specifically avoiding or minimising the risk of harm. Following this principle

means the person receiving care does not suffer injury caused by the treatment, although it is recognised that most medicines involve potential for harm, even if minimal. For example, vaccinations hold potential for anaphylaxis, leading to death, but the risk of this occurring is quantitively negligible. Where people are apprised of the risks of treatment this should be balanced with an explanation of the risks of no treatment. For example, prescribing an antibiotic for a suspected infected laceration should show benefit in reducing pain, redness, swelling exudate and prevent sepsis, but risks allergic reaction or microbial resistance (NICE, 2017, NICE, CKS, 2021b). Conversely, not treating with antibiotics may cause wound deterioration, damage to surrounding skin and potentially cellulitis leading to sepsis (NICE, CKS, 2021b, 2021c). The key principle of non-maleficence is that the harm is not disproportionate to the benefits of treatment. As some harm is unpredictable, previous experience may influence our decision-making and perception of risk. If the prescriber had witnessed a significant adverse effect, this could influence their choice of treatment in the future. For example, they may have witnessed or known of a relatively young woman having a life-changing stroke as a side-effect of the combined oral contraceptive (BNF, JFC) which influences their contraception advice. With the example of compression bandaging, most nurses using this treatment will have seen the damage to skin and tissues caused by uncontrolled exudate levels making it difficult to agree with the person's decision to decline this therapy. As a prescriber it is important to note that harm can be due to error (Elliot et al., 2018), side-effects, or interactions and with more than 50% of older people having two or more long term conditions (Kingston et al., 2018), prescribing is rarely undertaken in isolation.

The Hippocratic Oath places 'do no harm' above all else (Smith, 2005). Nightingale (1863) suggests do no harm as the first requirement of a hospital, and research by Page (2012) found non-maleficence to be unambiguously the most important ethical principle to practitioners. However, in law a person's autonomy is seen as paramount (BMA, 2020) and Gillon (2003) suggests autonomy 'trumps' all other principles. NICE (2019) state there is an ethical imperative for shared decision making, based on the fundamental moral principles of respecting the person's autonomy (the ability to make one's own decisions). Promoting autonomy means respecting the decision-making for people assessed as having mental capacity and enabling individuals as far as possible to make reasoned and informed choices.

However, conflict between non-maleficence and autonomy can pose a moral dilemma for practitioners, particularly when it involves choices likely to be harmful. A stark example is when someone assessed as having mental capacity refuses a potentially life-saving intervention (such as mechanical ventilation) or requests a potentially life-ending action (e.g., withdrawing a feeding tube). Varkey (2021) identifies this type of conflict between the principles of beneficence (or non-maleficence) and autonomy to be highly significant and that clear communication is imperative. Autonomy requires active listening and providing the opportunity to have views and choices heard and considered. Autonomy can be partial, for example if a person has been legally deemed as not having the mental capacity for certain treatment decisions (DCA, 2013). From an ethical perspective, people lacking capacity should stay at central to decision-making with their views respected as far as possible (Griffith and Tengnah, 2012, NICE, 2018).

A prescriber also needs to consider deontology (doing one's duty) versus utilitarianism (doing the greatest good for the greatest number). Deontology is based on rights and duty and involves doing the right thing without regard to whether the end consequences are good or bad (the means justifies the ends) (Mandal et. al. 2016). Utilitarianism is 'ends based'; and involves acting without regard to whether the way you achieve a good thing is right or wrong (the ends justify the means). A practical example of how these contrasting theories can be applied to prescribing is in considering the principles underpinning NICE guidance (NICE, 2020). Best practice as well as an economic analysis to show the cost-effectiveness of treatments is considered when developing guidelines (NICE, 2019) which can be seen as utilitarian because the purpose is to fairly distribute resources and enable the greatest number of people to be treated (Marseille and Kahn, 2019). This can come into conflict with duty-based care when a particular treatment is not approved by NICE, or a local formulary, but is the best treatment for the individual patient to whom you owe a duty of care. As a prescriber, part of the duty to individual patients involves advocating for on their behalf to change the guidelines and formularies as appropriate. This links to the 'cost-effectiveness' in the RAPID-CASE model, where part of this advocacy may involve collecting data to evidence a potential cost-benefit.

Conclusion

These two articles highlighted core professional, legal and ethical factors for prescribing, with some practical examples provided. As practice demand for safe and effective prescribers grows, it is important to continually update and critically reflect on these aspects of practice. The use of professional frameworks such as the RPS (2021) CFAP and models such as RAPID CASE (Gould and Bain 2022) can help to support prescribing practice. Critical consideration of the professional, legal, and ethical dimensions of prescribing is highly pertinent when the boundaries of practice scope are uncertain or variable such as in the recent COVID-19 pandemic.

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